

FAST-1 fusion protein. Group III relates to an in vitro binding assay using a Smad2 and FAST-1 protein. Group IV relates to an in vitro binding assay using a Smad3 and FAST-1 protein.

A restriction of claims requires that the claims be both independent and distinct (M.P.E.P. 802). Restriction is only proper if it can be shown that: (1) the claims belong to separate classifications; (2) a different field of search would be required; or (3) the claims have a separate status in the art (*e.g.*, as shown by citing patents that are evidence of such separate status or by showing a separate field of search) (MPEP 808.02). Applicants assert that the restriction in the parent case has not established all of these bases in support of the restriction requirement. The below remarks are divided into two sections: 1) lack of proper combination of groups I and II and of groups III and IV; and 2) lack of proper combination of groups I or II with groups III or IV.

I. Groups I and II and Groups III and IV are Improperly Subject to Restriction

The Examiner has classified Groups I and II in the same class and sub-class. Likewise, the Examiner has categorized groups III and IV in the same class and sub-class. Groups I and II recite a reporter gene assay for the detection of interactions between FAST-1 and either Smad-2 or Smad-3. Likewise, groups III and IV recite an *in vitro* binding assay for the detection of interactions between FAST-1 and either Smad-2 or Smad-3.

Applicants respectfully submit that the restriction in the parent case improperly restricted groups I and II and Groups III and IV because the claims in the groups are not independent. The M.P.E.P. states: "The term "independent" (*i.e.*, not dependent) means that there is no disclosed relationship between the two or more subjects disclosed, that is, they are unconnected in design, operation of effect, for example: (1) species under a genus which species are not useable together as disclosed: or (2) process and apparatus incapable of being used in practicing the process." (M.P.E.P. 802.01). The claims in groups I and II and in groups III and IV have alternative elements (Smad-2 and Smad-3) that are useful in the same method disclosed (*e.g.*, detecting compounds capable of modulating TGF- β signalling). As described below, Smad-2 and Smad-3 are exemplary FAST-1 binding partners that serve the same purpose (*e.g.*, use in detecting compounds capable of modulating TGF- β signalling).

Indeed, the claims of groups I and II as well as III and IV could be rewritten as single groups of claims, for example in Markush format. The MPEP states that "Broadly, unity of invention exists where compounds included within a Markush group (1) share a common utility and (2) share substantial structural feature disclosed as being essential to that utility." MPEP 803.02. The common utility of detecting compounds capable of modulating TGF- β signalling is clearly shared by the claims. Indeed, Smad-2 and Smad-3 are exemplary known binding partners of TGF- β that share substantial structural features (the ability to bind to TGF- β) and a common utility (the ability to bind to TGF- β) (See e.g., Specification, pg. 20, lines 1-10). Indeed, each set of claims could be written as one independent claim reciting the term "FAST-1 binding partner" with the choice of FAST-1 binding partners provided in dependent claims.

Applicants assert that the claims in Groups I and II and in Groups III and IV, in addition to not being independent, are also related. The M.P.E.P. states "The term "distinct" means that two or more subjects as disclosed are related, for example, as combination and part (subcombinations) thereof, process and apparatus for its practice, process and product made, etc., but are capable of separate manufacture, use of sale as claimed, AND ARE PATENTABLE (novel and unobvious) OVER EACH OTHER...." (M.P.E.P. 802.01) Groups I and II and Groups III and IV, as described above, have common uses (e.g., methods for the detection of compounds capable of modulating TGF- β signalling).

Furthermore, the fact that the claims are in the same class and sub-class does not require that separate searches be performed. The restriction in the parent case has not shown that a separate field of search is required. Thus, Applicants assert that the claims in Groups I and II and the claims in Groups III and IV are not sufficiently independent and distinct to warrant separate searches, and should be combined.

II. Groups I/II and Groups III/IV are Improperly Subject to Restriction

As described above, the Applicants assert that the restriction in the parent case improperly restricted groups I and II and groups III and IV. Applicants further assert that the restriction in the parent case improperly restricted Groups I or II (hereinafter Groups I/II) from Groups III or IV (hereinafter Groups III/IV). Groups I/II describe a reporter assay for the identification of compounds capable of modulating TGF- β signalling, while Groups III/IV

describe an in vitro binding assay for the identification of compound capable of modulating TGF- β signalling. Both sets of claims describe assays that measure a compound's ability to interfere with the binding of FAST-1 to Smad-2 or Smad-3.

One can apply the same analysis as that described above, resulting in the same conclusion, that is, the claims in Groups I/II and III/IV are neither independent nor unrelated. In regard to the aforementioned groups of claims, the Examiner states: "The following pairwise combination of methods are independent and distinct, wherein each member of a pair performs different functions, using different starting materials and/or process steps and/or with different outcomes." (Office action mailed 6/24/99, page 3). Applications respectfully disagree. As described above, both Groups I/II and Groups III/IV describe methods having the same function and outcome (detecting compounds that modulate TGF- β signaling) and measuring the same interaction (FAST-1 and either Smad-2 or Smad-3). Indeed, both methods are described in the specification under one heading entitled "Screens for Compounds Which Modulate TGF- β Superfamily Signalling" (Specification, pg. 19, line 23). In addition, as described above, one could write a single independent claim that encompassed the claims of both groups (*e.g.*, a claim to a method of detecting compounds that modulate TGF- β superfamily signaling by detecting compounds that inhibit the binding of FAST-1 to Smad-2 or Smad-3, where the claim did not specify the type of assay used to detect the binding).

The restriction in the parent case provided no reasons as to why the above groups of claims are deserving of separate status in the art or are in a different field of search. Nor did the restriction in the parent case provide any reasons as to why the claims are independent and distinct, as thus worthy of a separate classification. The M.P.E.P. states "Examiners must provide reasons and/or cite examples to support conclusions...." (M.P.E.P. 803). Thus, Applicants assert that the Examiner has improperly restricted groups I/II and III/IV.

CONCLUSION

For the reasons set forth above, it is respectfully submitted that Applicants' claims not be restricted. Should the Examiner believe that a telephone interview would aid in the prosecution of this application, Applicants encourage the Examiner to call the undersigned collect at (608) 218-6900.

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